

REMARKS

This is in response to the Official Action of March 26, 2003 for the above-identified application. Claims 1-20 are pending in this application.

Claims 1 and 10 have been amended as is further discussed below. The amendments do not constitute new matter. Claims 2, 7, 8, and 16 have also been amended to conform with Claims 1 and 10. Support for the amendments relating to insoluble thrombocyte fragments in Claim 1 is found in the specification at page 4, lines 3-5. Support for the amendments relating to freezing and lyophilization of the thrombocyte fragments can be found at page 3, line 30 to page 4, line 2.

Claim Rejections under 35 U.S.C. § 112

The Examiner has rejected Claim 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner states that the term "extended" is allegedly a relative term, rendering the claim indefinite. In addition, the Examiner alleges that it is not clear what the term "the same" is referring to in Claim 10, rendering the claim indefinite.

Claim 10 has been amended to delete the phrase "over an extended period over time" and to clarify the reference of "the same" to the growth factors. Applicants submit that amended Claim 10 particularly points out and distinctly claims the subject matter. As a result, applicants request the withdrawal of the rejection of Claim 10 under 35 U.S.C. § 112, second paragraph.

Claim Rejections under 35 U.S.C. § 103

The Examiner has maintained the rejections over Claims 1-20 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,902,608 (Read et al.) and U.S. Patent No. 5,589,462 (Patat et al.) in view of U.S. Patent No. 5,618,663 (Delmas), and U.S. Patent No. 5,618,663 (Dimoudis et al.).

The Examiner alleges that Read et al. teaches a sterile surgical composition comprising thrombocytes containing growth factor, where the thrombocytes may be prepared by lyophilization or deep-freezing without the requirement of albumin. The Examiner alleges that Patat et al. teach a medicinal product for topical application to wounds comprising frozen growth factor-containing thrombocytes. The Examiner further alleges that Patat et al. teach thrombocytes as a known source of growth factors and that other components of a platelet extract such as fibrinogen, thrombin and collagen are known for the promotion of wound healing. The Examiner alleges that Delmas teaches the inactivation of viruses in therapeutic thrombocyte products and Dimoudis et al. teach the utility of epithelial cells in wound healing compositions. The Examiner further alleges that it would be obvious to one of skill in the art to make a sterile platelet factor-enriched thrombocyte composition with the inactivation of viruses and by the addition of other known healing components such as an epithelial cell.

Applicants respectfully disagree. As set forth in *Graham v. Deere*, a finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and content of the prior art, the level of skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been

obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. John Deere, Inc.*, 383 U.S. 1 (1966). The art must provide both the suggestion and a reasonable expectation of success. *In re Vicki*, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The prior art reference(s) must teach or suggest all the claim limitations. Both the suggestion and a reasonable expectation of success must be present in the references.

Amended Claim 1 relates to a medicinal product for topical use for the promotion of wound healing, which comprises insoluble thrombocyte fragments, wherein said insoluble thrombocyte fragments (i) contain growth factors and are capable of releasing the growth factors, (ii) have been prepared by a method selected from the group consisting of lyophilization and freezing; and (iii) have been subjected to a process selected from the group consisting of virus partitioning and virus inactivation. In particular, Claim 1 has been amended to expressly recite a product comprising "insoluble thrombocyte fragments" wherein the fragments contain growth factors and are capable of releasing the growth factors. The instant specification defines such thrombocyte fragments as constituents of insoluble fractions isolated from thrombocytes through a range of separation techniques, which would be known to one of skill in the art. (specification, page 4, lines 3-5). To prepare the composition of the present invention, a thrombocyte suspension is subjected to the steps of photodynamic virus inactivation or solvent detergent treatment (page 5, line 21-25; page 8, lines 4-24), freezing, and lyophilization.

In contrast, Read et al. does not disclose or suggest the use of thrombocyte fragments or insoluble constituents of thrombocytes. In fact, Read et al. focuses on careful preparation and reconstitution of platelets in order to avoid cell lysis, teaching the use of whole

cells, rather than insoluble thrombocyte fragments, as presently claimed (col. 3, lines 6-10).

Thus, Read et al. teaches away from the use of insoluble cellular components. Also, Read et al. does not teach the steps of virus inactivation, or lyophilization, and thus fails to disclose required elements of the presently claimed composition.

Patat et al. also does not teach the presently claimed composition, as it does not teach the steps of virus inactivation and lyophilization.

Delmas is directed to a filtrate of a thrombocyte cell suspension, wherein the filtrate or supernatant is subjected to virus inactivation. The method taught by Delmas is vastly different because the supernatant is derived only from the secreted thrombocyte proteins, whereas the insoluble thrombocyte fragments may comprise constituents that are cellular or secreted. In addition, Delmas does not teach or provide motivation for required elements of presently claimed composition which comprises insoluble thrombocyte fragments, and prepared using the steps of freezing and lyophilization.

Dimoudis et al. discloses the use of epithelial cells, including keratinocytes, fibroblasts and endothelial cells as components of a biomaterial for the promotion of wound healing. There is no mention of the use of thrombocytes in the cited reference. Dimoudis et al. do not teach a medicinal product for topical use for the promotion of wound healing, which is made from insoluble thrombocyte fragments by lyophilization, freezing, virus partitioning and virus inactivation.

None of the references teach, alone or in combination, all the required limitations of the amended claims, i.e. a medicinal product for topical use for the promotion of wound

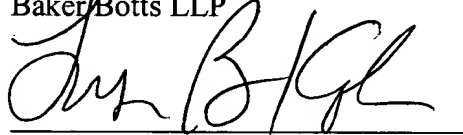
healing, which comprises insoluble thrombocyte fragments, wherein said insoluble thrombocyte fragments (i) contain growth factors and are capable of releasing the growth factors, (ii) have been prepared by a method selected from the group consisting of lyophilization of the thrombocyte fragments and freezing of the thrombocyte fragments; and (iii) have been subjected to a process selected from the group consisting of virus partitioning and virus inactivation.

Furthermore, there is no suggestion to combine the cited references to generate the presently claimed medical composition, and thus there is no reasonable expectation of success. Therefore, applicants respectfully request the withdrawal of the rejection of claims 1-20 under 35 U.S.C. § 103 (a).

CONCLUSION

Based on the foregoing amendments and remarks, applicants submit that the present application is in condition for allowance. A Notice of Allowance is respectfully requested. Applicants request a one month extension of time and enclose herewith the required fee pursuant to 37 C.F.R. § 1.17(a)(1). Should any additional fees be required in connection with this response, the Commissioner is hereby authorized to charge Deposit Account Number 02-4377. A duplicate of this page is enclosed.

Respectfully submitted,
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